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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/465,322	06/05/95	SODERLUND	H A28203-A-FWC
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18M2/1210
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EXAMINER

MYERS, C

ART UNIT

PAPER NUMBER

1807

DATE MAILED:

12/10/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.

08/465,322

Applicant(s)

Soderlund et al

Examiner

Carla Myers

Group Art Unit

1807



THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☒ expires six months from the mailing date of the final rejection.
- b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☒ Appellant's Brief is due two months from the date of the Notice of Appeal filed on Nov 14, 1997 (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Nov 14, 1997 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

- ☒ The proposed amendment(s):

- ☒ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
- ☐ will not be entered because:
- ☐ they raise new issues that would require further consideration and/or search. (See note below).
 - ☐ they raise the issue of new matter. (See note below).
 - ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
 - ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

- ☒ Applicant's response has overcome the following rejection(s):
The rejection of claims 51-68 under 35 USC 112, first paragraph.

- ☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

- ☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attachment

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: NONE 54-62Claims objected to: NONEClaims rejected: 51-68 51-53, 63-68

- ☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.
- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Other

Art Unit: 1807

ATTACHMENT TO ADVISORY:

Applicants arguments presented in the response of Paper No. 10 have been fully considered but are not persuasive to overcome all pending grounds of rejection for the following reasons:

1. Claim 68 stands rejected under 35 U.S.C. 112, second paragraph as indefinite and vague over the recitation of "wherein the oligonucleotide primer is hybridized to the target" because it is not clear as to whether the claimed reagent itself is present in a form in which it is hybridized to the target nucleic acid or if it is only a property of the claimed reagent that it is capable of hybridizing to the target nucleic acid adjacent to the predetermined position.

Applicants state that the claims must be read through the eyes of one of skill in the art and in light of the specification and thereby it is clear what is intended to be meant by the claims. However, there is no limitation in the claims or teachings in the specification which clarify the intended limitation of claim 68. It is maintained that it is not clear as to whether applicants intend to claim a double-stranded hybrid oligonucleotide in which the primer is bound to a target nucleic acid (as is inferred by the recitation that the primer "is" bound to a target nucleic acid) or if applicant intends to claim a primer that has the property of being capable of binding to a target nucleic acid (as is inferred by the recitation that the claimed reagent is a primer, rather than a product formed by the binding of a primer to a target).

2. Claims 51, 53, 64-66 and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Erlich.

Art Unit: 1807

In summary, in the response of Paper NO. 10, Applicants traversed this rejection by stating that Applicants invention does not require the inclusion of a hybridization step to determine if nucleotide variation is present but requires the use of a reagent , i.e. a primer which hybridizes adjacent to the target region. However, the fact that the method of Erlich is different from that of Applicants is not relevant here because the claims are drawn to products and not to methods. A comparison is made only between the product of Erlich and the product of the instant invention. The oligonucleotides of Erlich have the exact same properties as the reagents of the instant invention. The primer of Erlich, when hybridized to the target nucleic acid, is adjacent to the variable nucleotide, such that extension of the primer at the 3' end results in the incorporation of a variable nucleotide. Applicants attention is drawn to col. 29 and 30 of Erlich wherein the position of the DB01 primer is clearly shown, such that the primer hybridizes 3' to the CTT codon, which consists of a variable nucleotide since this codon may also be present as GTG. Therefore, it is a property of the DB01 primer of Erlich that it hybridizes to a segment of the target adjacent to a variable nucleotide. It is again pointed out that the recitation of the intended use of the primers of the instant invention does not carry weight.

3. Claims 52, 63 and 67 are rejected under 35 U.S.C. § 103 as being unpatentable over Erlich (U.S. Patent No. 5,310,893).

In summary, Applicants traverse this rejection by stating that the Examiner has misunderstood the teachings of Erlich. It is asserted that Erlich doesn't teach a primer for detecting the presence of a specific nucleotide at a predetermined position in a target nucleic acid.

Art Unit: 1807

Applicants go on to further compare the methodology disclosed in the instant specification with the methodology disclosed by Erlich.

However, it is pointed out that the claims are not drawn to methods, but rather are drawn to products. The recitation in the claims of the intended use of the product does not carry weight with respect to the issue of obviousness. The question is only one of whether the instant products are obvious in view of the teachings of Erlich. That is, the comparison is made only between the functional and structural limitations of Applicants product and the product of Erlich. Again, Erlich teaches an oligonucleotide DB01 primer which hybridizes 3' to the CTT codon, which consists of a variable nucleotide since this codon may also be present as GTG. Therefore, it is a property of the DB01 primer of Erlich that it hybridizes to a segment of the target adjacent to a variable nucleotide. The oligonucleotide of Erlich differs from the claimed oligonucleotide only in that Erlich does not specifically exemplify a DB01 primer having attached thereto an "attachment moiety" through which the primer can be immobilized or immobilization of the primer and the amplification product onto a solid support. However, Erlich does teach that primers useful for amplifying variable nucleotides can be modified so as to attach labels thereto, including labels which can be used to capture the primer and facilitate immobilization of the primer onto a solid support (see col. 5).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the amplification primer of Erlich so as to have attached a moiety allowing for the immobilization of the primer in order to have accomplished the expected advantage of generating a primer which could easily immobilized

Serial Number: 08/465,322

-5-

Art Unit: 1807

onto a solid support to have allowed for the rapid and efficient separation and isolation of the nucleic acids comprising the amplification primer from other nucleic acids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for this Group is (703)-305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Carla Myers

December 8, 1997

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER
GROUP 1800